IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

VEIN & WELLNESS GROUP, LLC,
166 Defense Hwy #101
Annapolis, Maryland 21401,

Plaintiff,

v.

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services,
200 Independence Ave., S.W.
Washington, DC 20201

Defendant.

Case No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR ADMINISTRATIVE REVIEW

Plaintiff Vein & Wellness Group, LLC (VWG) brings this action against Defendant Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services. Plaintiff makes the following allegations based on the investigation of counsel and on information and on personal knowledge.

I. JURISDICTION

1. This Court has jurisdiction over this action pursuant to 42 U.S.C. §§ 405(g) and 1395ff. VWG is filing suit after a final decision(s) of the Medicare Appeals Council (acting on behalf of the Secretary) denying coverage of Medicare claims (and, therefore, VWG has exhausted its administrative remedies), the amount-in-controversy is more than $1,760 (42 U.S.C. §§ 1395ff(b)(1)(E)(i) and 1395ff(b)(1)(E)(iii)), and this suit was filed within 60 days of the Secretary's final decision (plus five days for mailing). *See* 42 C.F.R. § 405.1016(f).

2. Venue is proper in this district pursuant to 42 U.S.C. § 405(g) and 42 U.S.C. § 1395ff(b)(2)(c)(iii) because this action is being brought in the District of Maryland, where VWG is incorporated and has its principal place of business.

II. PARTIES

3. Plaintiff Vein & Wellness Group LLC is a Maryland limited liability corporation with its principal place of business in Annapolis, Maryland. VWG is an approved provider of Medicare services.

4. Defendant Xavier Becerra sued in his official capacity as the Secretary of Health and Human Services.

III. FACTUAL BACKGROUND

5. This case concerns 158 vein surgeries (MOCA) performed by VWG in the period 2014-15 for Medicare Part B insureds who have assigned their claims for Medicare Part B reimbursement to VWG.

Medicare Part B and Appeal Process

6. Medicare Part B (the portion of Medicare relevant here) is a "voluntary insurance program." *See* 42 U.S.C. §§ 1395j ("voluntary insurance program") and 1395k. Medicare Part B insureds pay monthly premiums in exchange for coverage of qualifying claims. *See* 42 U.S.C. §§ 1395r and 1395s. If a claim qualifies, then the insured is "entitled" to Medicare Part B payment of the claim. *See* 42 U.S.C. §§ 1395ff(a)(1)(A) ("entitled to benefits") and 1395k(a)(1)/(2) ("entitlement to have payment made to him or on his behalf").

7. Medicare Part B claims are subject to a five-level appeal process. The insured begins by submitting a claim. *See* 42 C.F.R. §§405.920-928. If denied, the insured can request

"redetermination." *See* 42 C.F.R. §§405.940-958. If the claim is still denied, the insured can request "reconsideration." *See* 42 C.F.R. §§405.960-978.

8. If the claim is still denied, the Secretary must provide "hearings" for appeals to the "same extent" as is provided for in Social Security hearings. *See* 42 U.S.C. §1395ff(b)(1)(A) (citing 42 U.S.C. §405(b)).

9. The Secretary's regulations limit the issues considered at the hearing before the ALJ. Pursuant to 42 C.F.R. § 405.1032(a), the issues the ALJ may consider are only those that were not entirely decided in favor of the appellant in the initial denial, redetermination, and/or reconsideration and "specified in the request for hearing."

10. The Secretary has detailed regulations on how new issues may be raised. *See* 42 C.F.R. § 405.1032(b).

11. The effect of these regulations is to preclude the insured from being sandbagged by new issues at the hearing.

12. After the hearing, the ALJ issues a written decision, which includes findings of fact and conclusions of law and must be based on the evidence admitted at the hearing. *See* 42 C.F.R. §405.1046.

13. If the Secretary is dissatisfied with the ALJ's decision (and participated in the ALJ hearing), the Secretary can appeal to the Medicare Appeals Council (MAC). *See* 42 C.F.R. §§405.1100-1140. The Secretary can appeal an ALJ's decision on so-called "own motion" review. *See* 42 C.F.R. §405.1110.

14. Finally, an insured who is dissatisfied with the MAC's decision may seek judicial review. *See* 42 U.S.C. §1395ff(b)(1)(A).

The Claims at Issue in this Case

15. The claims at issue were grouped into three appeals - Medicare Appeal Nos. 1-5712041048, 1-5736021004, and 1-5712041192.

16. All the claims at issue were initially paid.

17. Thereafter, Medicare contended that the claims were improperly paid, denied the claims, and sought recoupment.

18. This determination was appealed for redetermination where all the claims were denied again.

19. At reconsideration, all the claims were again denied on the grounds that the wrong billing code had been used.

20. In correspondence dated March 13 and 14, 2017, counsel for VWG requested ALJ hearings in each of the appeals.

21. The requests were limited to the issue of the alleged coding error.

22. Thereafter, ALJ Lori May held a single hearing on May 17, 2021, and issued three decisions on August 16, 2021.

23. For 152 of the claims, the ALJ found that the denials based on allegedly using the wrong billing code were improper and ordered coverage.

24. However, for 6 of the claims, the ALJ denied coverage on the new grounds of lack of documentation.

25. On October 8, 2021, CMS filed a "referral" for MAC "own motion review" of the ALJ's decisions.

26. In particular, rather than the alleged wrong billing code, CMS alleged that the ALJ erred by not considering the new issue of whether the procedures were "medically reasonable and necessary."

27. On October 12, 2021, VWG timely appealed the denial of the six claims to the Medicare Appeal Council (MAC) on the grounds that the ALJ's decision was based on a new issue that was not the basis for denial below, not the subject of VWG's request for hearing, and not properly noticed.

28. In addition, VWG alleged that the documentation was, in fact, present.

29. Finally, on December 14, 2021, the MAC issued a decision denying VWG's appeal, reversing the ALJ as to all the other claims, and rejecting them.

30. In particular, the MAC contended that the ALJ erred by not considering an issue that was not the subject of the denials below, VWG's request for an ALJ hearing, or a properly noticed issue – i.e., whether the procedures were "medically reasonable and necessary."

31. The MAC did not address VWG's appeal.

32. This suit follows.

IV. CAUSES OF ACTION

COUNT I
Violation of 5 U.S.C. § 706(1)
(unlawfully withheld or unreasonably delayed)

33. Paragraphs 1-32 are incorporated by reference as if fully set forth herein.

34. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's decision as unlawfully withheld or unreasonably delayed and unsupported by the evidence, and issue an order finding that the claims are covered by Medicare and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT II
Violation of 5 U.S.C § 706(2)(A)
(arbitrary and capricious, abuse of discretion, not in accordance with law)

35. Paragraphs 1-34 are incorporated by reference as if fully set forth herein.

36. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's decision as arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with the law, and issue an order finding that the claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT III
Violation of 5 U.S.C § 706(2)(C)
(in excess of statutory jurisdiction, authority, or limitations or short of statutory right)

37. Paragraphs 1-36 are incorporated by reference as if fully set forth herein.

38. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's decision as in excess of the Secretary's authority and limitations and short of Plaintiff's statutory rights and issue an order finding that the claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT IV
Violation of 5 U.S.C § 706(2)(D)
(without observance of procedure required by law)

39. Paragraphs 1-38 are incorporated by reference as if fully set forth herein.

40. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's decision as done without observance of the procedure required by law (*e.g.*, the limitation on issues before an ALJ) and issue an order finding that the claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT V
Violation of 5 U.S.C § 706(2)(E)
(not supported by substantial evidence)

41. Paragraphs 1-40 are incorporated by reference as if fully set forth herein.

42. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's decision as not supported by substantial evidence and issue an order finding that the claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

V. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that this Court:

A. Enter an order:

(1) Finding that the claims are covered; and

(2) pursuant to 42 U.S.C. § 405(g) (fourth sentence) remanding this matter to the Secretary with instruction to provide coverage for claims at issue in this case; and

B. Award attorney's fees and costs to Plaintiffs as permitted by law; and

C. Such further and other relief (including nominal damages) this Court deems appropriate.

Dated: February 16, 2022

Respectfully submitted,

/s/Daniel Z. Herbst
Daniel Z. Herbst (MD Bar No. 17510)
REED SMITH LLP
1301 K Street, NW
Suite 100-East Tower
Washington, DC 20005
(202) 414-9232
(202) 414-9184
dherbst@reedsmith.com

And

PARRISH LAW OFFICES
James C. Pistorino (*Pro Hac Vice Motion forthcoming*)
788 Washington Road
Pittsburgh, PA 15228
Telephone: (412) 561-6250
Facsimile: (412) 561-6253
james@dparrishlaw.com

Attorneys for Plaintiff